

REMARKS

Reconsideration and allowance in view of the foregoing amendment and the following remarks are respectfully requested.

Claims 1-3, 5, 7, 10, 15-17 and 20 remain pending, claims 1, 17 and 20 being currently amended.

The Examiner has rejected claims 1, 3, 5, 15 and 16 under 35 U.S.C. 102(e) as being anticipated by Sjoberg (US patent 6,491,952) for a disclosure of "cholesterol lowering baked cakes of 18-20 grams each containing 0.5g of sitosterol or sitostanol and oat flakes." Reconsideration and withdraw of the rejection is earnestly solicited.

As indicated previously, the standard of review under this section is well founded and in this regard see, Kalman v. Kimberly-Clark Corp., 713 F. 2d 760, at 771, 218 USPQ 781, at 789 (1983), where the Court of Appeals for the Federal Circuit held:

"A party asserting that a patent claim is anticipated under 35 USC 102 must demonstrate, among other things, identity of invention. In cases like this, identity of invention is a question of fact...(citation omitted) and one who seeks such a finding must show that each element of the claim in issue is found, either expressly described or under the principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice."

Sjoberg does not disclose the use of a dietary fiber in combination with a sterol/stanol or derivative there of, with the dietary fiber being present in an amount ranging from 1-3 grams per serving size and having a protein content of at least 8%, as currently amended. Support for the present amendment is found at page 6 of the specification.

The purpose of Sjoberg is to increase the availability of the sterol/stanol to aid in cholesterol reduction.

"We have now shown that it is not necessary to esterify sterols and stantols to be able to distribute them in a sufficient high concentration in a monomolecular, low associated or "cluster form" to reach necessary daily doses" (Sjoberg column 1, lines 36-40). "The surface of sterols and/or stanols accessible to the stomach thus becomes extremely large" (Sjoberg, column 1, lines 61-63).

It is therefore unlikely, that Sjoberg would be interested in including other components that may bind or interact with the sterol/stanol to thus partially conceal or interfere with the desirable properties of the cholesterol-lowering ingredient. Indeed, if Sjoberg was involved in the commercial production of sterol/stanol derivatives, as would be suggested in light of the desire to increase the availability of the component, one would not want to introduce other components to the formulation which may detract from the possible sale or use of the commercial enterprise in which one is actively engaged.

In addition, the Examiner admits on page 3 of the Official Action that "Sjoberg fails to explicitly teach products that lower LDL (emphasis added)." As such, the reference cannot anticipate the claims of the present invention, as each and every element is not present in a single prior art reference.

As such, it is the position of applicant that the anticipation rejection is moot in view of the foregoing amendment and argument, as well as the Examiner's own admission, as there is no single reference that discloses each and every element of the claimed invention.

Claims 1-3, 5, 7, 10, 15-17 and 20 have been rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Sjoberg in view of James (US patent 6,020,324). Reconsideration and withdraw of the rejection is earnestly solicited.

As indicated above, the teachings of Sjoberg are directed to increasing the availability of sterols/stanols to aid in cholesterol lowering. James suggests the use of dietary fiber, namely beta-glucan, for use in cholesterol reduction. Neither of the references teach or suggest combining dietary fiber with a protein content of at least 8% with a sterol/stanol to aid in cholesterol reduction. Each reference promotes the benefit of its particular ingredient and neither suggests that additional benefit can be obtained through synergistic use with another ingredient or component.

The Examiner in the present Official Action suggests that it is obvious “to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form [a] third composition that is to be used for the very same purpose” (Official Action at page 3).

Applicant respectfully disagrees with the Examiner’s contention that the teachings of Sjoberg are combinable with James to produce the presently claimed invention. As applicant has already indicated, Sjoberg is directed to maximizing the benefit of the sterol/stanols and increasing the availability of the sterol/stanol in the mixture and as a commercial entity is interested in promoting its ingredient offering.

James is similarly interested in promoting the benefit of its component ingredient. This is further manifested in the fact that the listed assignee of James is a company engaged in the provision of “products and services to the cosmetic, personal care, pharmaceutical and biotechnology industries” (see website www.collabo.com). As such, one would not use the teachings of Sjoberg with James or any other reference where the benefit of the composition results from the synergies of the two components as opposed to the individual elements. Each of Sjoberg and James lack any motivational suggestion to make the alleged combination suggested by the Examiner.

Merely because references may be combined, does not render the combination appropriate absent sufficient motivation to do so. In order for a *prima facie* case of obviousness to exist, the prior art must teach the desirability of a modification or combination of the references. In order to establish *prima facie* obviousness, it is well settled that three basic elements must be met: there must be (a) some suggestion or motivation to combine the references or modify the reference teaching; (b) a reasonable expectation of success; and (c) the reference or references when combined must teach or suggest each claim limitation. Here the prior art does not suggest the references may be so modified and in this regard see, In re Fritch, 23 USPQ 2d 1780, 1783, 1784 (Fed. Cir. 1992), wherein the Court held:

“‘Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so.’ Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious ‘modification’ of the prior art. The mere fact that the prior art may be modified in the manner suggested by the examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. Wilson and Hendrix fail to suggest any motivation for, or desirability of, the changes espoused by the examiner and endorsed by the Board.”

The combination alleged by the Examiner to be present in the prior art simply does not manifest itself based on the teachings available in the references, as there is no motivation provided to make the combination. The combination of a dietary fiber having a protein content of at least 8% in combination with a sterol/stanol for lowering cholesterol is only gained through the use of hindsight obtained from applicant’s own teachings. It appears to applicants that the prior art has been cited and applied using applicants’ own specification as a road map.

In determining motivation to combine prior art references the nature of the problem to be solved must be taken into account as the Federal Circuit stated in In re Rouffet, 47 USPQ 2d 1453, 1458 (Fed. Cir. 1998):

“In other words the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.”

Applicants dispute the implicit premise for combining the cited documents. The evidence of a suggestion, teaching, or motivation to combine prior art documents may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. See Pro-Mold & Tool Co. v. Great Lakes Plastic, Inc., 75 F.3d 1568, 1573, 37 USPQ 2d 1626, 1630 (Fed. Cir. 1996), Para-Ordinance Mfg. V. SGS Imports Intern., Inc., 73 F.3d 1085, 1088, 37 USPQ 2d 1237, 1240 (Fed. Cir. 1995), although “the suggestion more often comes from the teachings of the pertinent references, In re Rouffet, 47 USPQ 2d 1453, 1456 (Fed. Cir. 1998) (“The Board must identify specifically...the reasons one of ordinary skill in the art would have been motivated to select the references and combine them.”) The range of sources available however does not diminish the requirement for actual evidence. That is, the showing to combine must be clear and particular. See C.R. Bard Inc. v. M3 Systems, Inc., 48 USPQ 2d 1225, 1232 (Fed. Cir. 1998). Broad conclusory statements regarding the teaching of multiple references, standing alone, are not “evidence.” McElmurry v. Arkansas Power & Light Co., 995 F.2d 1576, 1578, 27 USPQ 2d 1129, 1131 (Fed. Cir. 1993).

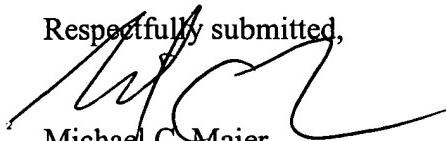
Soluble fiber and sterol/stanols have been known for many years, but the fact that no one heretofore has thought to create the combination in order to provide a beneficial ready to eat food product for cholesterol lowering suggest novelty of the invention rather than being obvious as suggested by the Examiner.

"As this Court has stated, 'virtually all [inventions] are combinations of old elements.' (citations omitted) ('Most, if not all, inventions are combinations and mostly of old elements.') Therefore, an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Further, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as the blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be 'an illogical and inappropriate process by which to determine patentability.' (citation omitted) In re Rouffet, 47 USPQ 2d 1453, 1457 (Fed. Cir. 1998)

There is simply no teaching, disclosure or suggestion of the novel combination of a soluble fiber in a ready to eat food product with a stanol/sterol to produce a cholesterol lowering food product.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and an early Notice to that effect is earnestly solicited. The Examiner is encouraged to contact the undersigned in the event any small matters remaining outstanding so as to eliminate the necessity of another action and response.

The Commissioner is hereby authorized to charge any fees associated with this response to our deposit account number 07-0900.

Respectfully submitted,

Michael C. Maier
Reg. No. 36,206

General Mills, Inc.
P.O. Box 1113
Minneapolis, MN 55440
(763) 764-2265
(763) 764-2268 (fax)